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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)		Application Number	09/974,712
		Filing Date	Oct 10, 2001
		First Named Inventor	Friddle, Carl Johan
		Art Unit	1647
		Examiner Name	Landsman, Robert S.
Total Number of Pages in This Submission	5	Attorney Docket Number	LEX-0251-USA

ENCLOSURES (Check all that apply)		
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Firm Name	Lexicon Genetics Incorporated		
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Printed name	Lance K. Ishimoto		
Date	April 26, 2005	Reg. No.	Reg. No. 41,866

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Appellant(s):	Turner, Jr. <i>et al.</i>	Group Art Unit: 1647
Application No.:	09/974,712	Appeal No.: 2005-0731
Filed:	10/10/2001	Examiner: R. Landsman
Title:	Polynucleotides and Polypeptides Encoding Human Ion Channel Proteins (As Amended)	Atty. Docket No.: LEX-0251-USA

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**RESPONSE TO ORDER UNDER 37 C.F.R. § 41.50(d)**  
**DATED MARCH 30, 2005**

**Mail Stop Appeal Brief - Patents**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Appellants acknowledge the receipt of the Order under 37 C.F.R. § 41.50(d) ("the Order") in the above-referenced case, mailed on March 30, 2005, which has been carefully reviewed and studied. Appellants herein respond as ordered.

A one month non-extendable time limit for response is set forth in the Order. The response is therefore timely filed, and Appellants believe no fees are due in connection with this response. However, the Commissioner is authorized to charge any required fees or credit any overpayment to Deposit Account No. 50-0892.

## RESPONSE

As stated in the Order by The Board, “we require Appellants to address the foregoing matters ‘considered to be of assistance in reaching a reasoned decision on the pending appeal’ 37 C.F.R. § 41.50(d)” (page 5, line 12) and “we require Appellants to explain why we should again address the same line of arguments in this case: since the same arguments were considered and thoroughly addressed in Appeal No. 2004-1732, why would the previous panel’s treatment of those arguments not be dispositive here?” (page 5, lines 1-4) . As directed by the Order, Appellants confine their response to those matters that differentiate the present Appeal from that of Appeal No. 2004-1732, decided on September 24, 2004 (Application No. 09/714,882). Applicants respectfully note that the instant Appeal Brief was filed prior to receipt of the decision in Appeal No. 2004-1732.

Appellants respectfully invite the Board to consider that the Appeal Brief in the present case describes a credible, specific, substantial, and well-established utility that has a different fact pattern and supporting evidence, and thus were not specifically briefed, in Appeal No. 2004-1732. First, Appellants respectfully point-out that pages 6-10 of the present Appeal Brief describe, *inter alia*, evidence of record that clearly establishes that the present application and claims meet the administrative requisites outlined in Example 10 of the Revised Interim Utility Guidelines Training Materials. Unlike the Appeal Brief in Appeal No. 2004-1732, the present Appeal Brief describes: 1) A sequence sharing over **99% percent identity at the protein level** over the entire length of the claimed sequence is present in the leading scientific repository for biological sequence data (GenBank); 2) That the identified sequence has been annotated by third party scientists *wholly unaffiliated with Appellants* as “*Homo sapiens* voltage-gated potassium channel KCNA7” (GenBank accession no. AAK63002 (see **Exhibit A** of the Appeal Brief); 3) That Applicants set forth in the specification as originally filed that the sequences of the present invention encode a novel mammalian ion channel protein (specification in title, on page 1, line 12 and on lines 24-28) that shares structural similarity with mammalian ion channel proteins, and particularly potassium channels and more particularly voltage-gated potassium channel proteins (specification on page 2, lines 2-4); 4) That Applicants set forth in the specification as originally filed that the presently claimed sequence has disease associations (particularly the cardiac related disorders high blood pressure, arrhythmia, and others at least at page 13, lines 22-24) which are consistent with the evidence provided in information provided by others in scientific publications (Bardien-Kruger,

S., *et al.*, Eur J Hum Genet, 10(1):36-43, 2002 and Kashuba *et al.*, Gene, 268(1-2):115-22, 2001 (CO on Form -1449); and 5) That the role of human ion channel proteins are well known to those of skill in the art and that this is particularly true for voltage-gated potassium channels. Given the scientific evidence of record, there can be no question that those skilled in the art would clearly believe that Appellants' sequence encode a novel human ion channel protein, particularly voltage-gated potassium channel proteins, specifically a variant of the voltage-gated potassium channel now known as KCNA7. Therefore, Appellants point out in the Appeal Brief that the present case directly tracks Example 10 of the Revised Interim Utility Guidelines Training Materials, which clearly establishes that a rejection under 35 U.S.C. § 101 as allegedly lacking a patentable utility and under 35 U.S.C. § 112, first paragraph as allegedly unusable by the skilled artisan due to the alleged lack of patentable utility is not proper when a full length sequence (such as the presently claimed sequence) has a similarity score greater than 95% to a protein having a known function (such as the over 99% identity between the presently claimed sequence and the Wnt-14 sequence, as discussed above). Thus, as set forth in the Appeal Brief, Appellants contend that the presently claimed sequence clearly meets the requirements of 35 U.S.C. § 101.

The facts and evidence supporting the clear and legally valid utilities described above were not discussed in Appeal No. 2004-1732. While Appellants acknowledge that Appeal No. 2004-1732 dealt with some issues of utility set forth in the present Appeal Brief, Appellants respectfully request that the Board consider that the evidence and facts of record in the present Appeal merit, if not logically require, an outcome opposite from that reached by the Board in Appeal No. 2004-1732. The Board is thus requested to consider that the prior rejection of *some* of Appellants' assertions of utility should not end the present inquiry, for, as clearly set forth by the Federal Circuit, and set forth in the present Appeal Brief, Appellants need only make one credible assertion of utility to meet the requirements of 35 U.S.C. § 101 (*Raytheon v. Roper*, 220 USPQ 592 (Fed. Cir. 1983); *In re Gottlieb*, 140 USPQ 665 (CCPA 1964); *In re Malachowski*, 189 USPQ 432 (CCPA 1976); *Hoffman v. Klaus*, 9 USPQ2d 1657 (Bd. Pat. App. & Inter. 1988)). Furthermore, Appellants respectfully submit that all issues relating to patentable utility are required to be raised and contested in order to preserve such issues for appeal to the Federal Circuit, which has not yet determined the broader legality of the Patent Office's imposition of a distinct and more onerous standard of utility for biotechnology sequence inventions.

Therefore, given that the facts and evidence supporting a number of assertions of utility are set forth by Appellants in the present Appeal Brief that were not addressed by the previous

merits panel in Appeal No. 2004-1732, Appellants respectfully request the Board to address all of the assertions of utility set forth by Appellants in the Appeal Brief in the present case, and to overrule the rejections of claims 1-3 and 5 under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph.

Respectfully submitted,

April 26, 2005

Date



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